



EC CERTIFICATE

National Health Service Blood & Transplant (NHSBT)

14 Estuary Banks
Liverpool L24 8RB UNITED KINGDOM

EC Certificate - Full Quality Assurance System Approval Certificate

Annex IV (excluding sections 4 and 6) of Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices

Scope of Certificate:

The design and manufacture of in vitro diagnostic medical devices for determining blood groups

Device Classifications:

**Annex II List A
Annex II List B**

Device Descriptions and Model Type:

Please refer to Attachments: 1, 2

We hereby declare that an examination of the full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subject, transposing Annex IV (with the exemption of sections 4 and 6) of Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive and is subject to periodic surveillance as required by 98/79/EC, Annex IV, Section 5. For Annex II, List A devices where they are covered by this certificate, an EC Design Examination certificate according to 98/79/EC, Annex IV, Section 4 is required. This certificate is issued with 2 attachments listing product references.

File Number	A18088	Cycle Start Date	December 12, 2018
Certificate Number	308.190322	Effective Date	March 22, 2019
Initial Issue Date	December 11, 2003	Expiry Date	March 11, 2023

Authorised by

Paul Daysh
Certification Manager
For and on Behalf of UL International (UK) Ltd



Notified Body
0843

IVDD A4 S3 FQ
00-MB-A0043 Issue: 15.0

Check Certificate
Status: [here](#)

UL International (UK) Limited
Wonersh House, The Guildway, Old Portsmouth Road,
Guildford, Surrey, GU3 1LR, United Kingdom



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Attachment 1 of 2

The products detailed below are covered under the scope of this certificate:

Model/Type	Classification	G/UMDN Code
A1rr cells Alsevers (10mL 2.8% suspension) PR012	Annex II List A	-
A2rr cells Alsevers (10mL 2.8% suspension) PR022	Annex II List A	-
Brr cells Alsevers (10mL 2.8% suspension) PR033	Annex II List A	-
OR1r cells Alsevers (10mL 2.8% suspension) PR044	Annex II List A	-
A1rr cells in CellStab (10mL 0.8% suspension) PR014	Annex II List A	-
A1rr cells in CellMedia PR015	Annex II List A	-
Brr cells in CellStab (10mL 0.8% suspension) PR035	Annex II List A	-
Brr cells in CellMedia PR036	Annex II List A	-
BR1r cells in Alsevers (10mL 2.8% suspension) PR034	Annex II List A	-
OR1r cells in CellStab (10mL 0.8% suspension) PR045	Annex II List A	-
OR1r cells in CellMedia PR046	Annex II List A	-
2 Cell antibody screen PR101	Annex II List B	-
2 Cell antibody screen in CellStab PR102	Annex II List B	-
2 Cell antibody screen in CellMedia PR103	Annex II List B	-
rr Cell antibody screen in CellStab PR106	Annex II List B	-
rr Cell antibody screen in CellMedia PR108	Annex II List B	-
r'r and r''r Cell antibody screen in CellStab PR107	Annex II List B	-
r'r and r''r Cell antibody screen in CellMedia PR109	Annex II List B	-
Antibody ID panel products in Alsevers PR141/144/201/211	Annex II List B	-
Antibody ID panel products in CellStab PR142/143	Annex II List B	-
Antibody ID panel products in CellMedia PR162/163	Annex II List B	-
Antibody ID panel products in LISP PR146	Annex II List B	-
Antibody ID panel products papainised in Alsevers PR154	Annex II List B	-
Antibody ID panel products papainised in CellStab PR152/153	Annex II List B	-
Antibody ID panel products papainised in CellMedia PR172/173	Annex II List B	-

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Attachment 2 of 2

The products detailed below are covered under the scope of this certificate:

Model/Type	Classification	G/UMDN Code
IgG coated cells PR092	Annex II List B	-
ZZAP Kit PN161	Annex II List B	-
Weak Anti-K Control PN043	Annex II List B	-
Weak Anti-c Control PN042	Annex II List B	-
Weak Anti-Fya Control PN044	Annex II List B	-
Weak Anti-D Control PN046	Annex II List B	-
AB Serum PN061	Annex II List B	-
3 Cell antibody screen PR121	Annex II List B	-
3 Cell antibody screen in CellStab PR122	Annex II List B	-
3 Cell antibody screen in CellMedia PR123	Annex II List B	-
3 Cell antibody screen papainised in Alsevers PR124	Annex II List B	-

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